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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,707	04/10/2001	James U. Morrison	26017-3	1778

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EXAMINER
WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
1623	8

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/829,707	MORRISON, JAMES U.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed October 15, 2002 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(C) New Claim 43 has been added.
(D) Claims 1 and 15 have been amended.
(E) Comments regarding Art Rejection have been provided drawn to
  (a) 102(b) and (e) rejection, which has been maintained for the reasons of record.
  (b) 103(a) rejection, which has been maintained for the reasons of record.

2. Claims 1-43 are pending in the case.

3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 43 discloses an acarbose formulation that does not include a lipase inhibitor. However, the instant application does not support this statement and therefore Claim 43 does not conform to the requirement of the first paragraph of 35 U.S.C. 112, which requires the specification to contain a written description of the invention. Hence, Claim 43 set forth new matter, which is improper under 35 U.S.C. 112, first paragraph.

6. Applicant's arguments with respect to claim 43 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

7. Claims 1-14 stand rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al (US Patent No. 6,309,663) for the reasons disclosed on pages 2 and 3 of the Office Action mailed July 9, 2002.

8. Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive. Applicants amended Claim 1 to indicate that the acarbose and sustained release matrix are combined to form a mixture and argues against the use of the Patel et al patent in the rejection of the claims on the ground that the Patel et al patent does not disclose combining the ingredients recited in the claims to form a mixture. Applicants argue that the sustained release matrix disclosed in the Patel patent is only used to coat or cover the acarbose, and thus does not form a mixture. This argument is not persuasive because Patel et al describes a coating procedure that involves enteric coating. See column 38, lines 53-57 of the Patel et al patent whereby "enteric coating" is described as "relating to a mixture of pharmaceutically acceptable excipients which is applied, combined with, mixed with or otherwise added to the hydrophilic therapeutic agent, enzyme inhibitor and/or absorption enhancing carrier" (which include acarbose). Also see column 38, line 12 of the Patel et al patent, whereby it is indicated that the dosage form release profiled of the composition may be selected as "a coated multiparticulate composition", which suggests that the particles of the composition are coated, further suggesting that the acarbose and sustained release matrix components used in the Patel et al patent are completely mixed. Furthermore, see column 38, lines 61-63 whereby Patel et al discloses that the coating may be applied through an aqueous dispersion or after dissolving in appropriate solvent, which is further indication that the coating used by Patel et al is part of a mixture. Accordingly, the rejection of Claims 1-14 under 35 U.S.C. 102(e) as being anticipated by the Patel et al patent is maintained for the reasons of record.

9. Claims 15-27 stand rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al (US Patent No. 6,309,663) for the reasons disclosed on pages 3 and 4 of the Office Action mailed July 9, 2002.

10. Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive. Applicants amended Claim 15 to indicate that the chemical composition comprising acarbose and sustained release matrix are combined to form a mixture and sets forth arguments therefor. However, this argument is not persuasive for the same reasons indicated above for the rejection of Claims 1-14 under 35 U.S.C. 102(e).

Applicants also amended the chemical composition of Claim 15 to indicate use to stimulate weight loss in a patient. Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note In re Tuominen, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. Accordingly, the rejection of Claims 15-27 under 35 U.S.C. 102(e) as being anticipated by the Patel et al patent is maintained for the reasons of record.

11. Claims 28-41 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bremer et al (US Patent No. 5,643,874) for the reasons disclosed on pages 4 and 5 of the Office Action mailed July 9, 2002.

12. Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive. Applicants argue against this rejection on the ground that the Bremer et al patent recites that glucosidase and/or amylase inhibitors, used in monotherapy in combination with a reduction diet bring about "practically no weight lose and further states it is the combined use of glucosidase and/or amylase inhibitors in combination with a lipase inhibitor that results in weight loss. Applicants argue that this statement in the Bremer et al patent teaches against Applicants claimed method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient. This argument is not persuasive since Applicants have not claimed the administration of acarbose, alone, to stimulate weight loss. This statement only indicate that the administration of acarbose alone do not stimulate weight loss and establishes that a composition comprising acarbose is required to stimulate weight loss. The acarbose formulation used by applicants comprises other ingredients, which is

anticipated by the Bremer et al patent. Arguments presented by Applicants with regard to the use a lipase inhibitor in the composition is not persuasive since the language set forth in the claims as currently written do not exclude the presence of other active ingredients with the claimed composition.

Applicants further argue against this rejection on the ground that the Bremer et al patent does not teach the use of a composition comprising acarbose and sustained release matrix, for the stimulation of weight loss. This argument is not persuasive since the Bremer et al patent discloses glucosidase and/or amylase inhibitors that can be manufactured as pharmaceutical compositions for combine use with a lipase inhibitor in the treatment of obesity (see column 1, line 27 and column 2, lines 1-3). The Bremer et al patent discloses that the glucosidase and/or amylase inhibitor may be selected as acarbose (see column 2, lines 5-12). Bremer et al discloses that the acarbose may be present in tablets that have controlled active substance release and increase residence time in the stomach (see Example D in column 6) which is within the meaning of the phrases "delayed release matrix" and "sustained release matrix" that is set forth in instant Claims 29 and 30. Accordingly, the rejection of Claims 28-41 under 35 U.S.C. 102(b) as being anticipated by the Bremer et al patent is maintained for the reasons of record.

13. Claims 15-27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bremer et al (US Patent No. 5,643,874) for the reasons already of record on page 5 of the Office Action mailed July 9, 2002.

14. Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive. The arguments presented by Applicants against the rejection of Claims 15-27, which is drawn to chemical compositions, is based on the use of the composition to stimulate weight loss in a patient. However, a difference in intended use cannot render a claimed composition novel. Note In re Tuominen, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. Accordingly, the rejection of Claims 15-27 under 35

U.S.C. 102(e) as being anticipated by the Bremer et al patent is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

15. Claims 28-42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer et al (US Patent No. 5,643,874) in view of Patel et al (US Patent No. 6,309,663) for the reasons already of record on pages 6 and 7 of the Office Action mailed July 9, 2002.

16. Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both references discloses pharmaceutical compositions comprising acarbose and sustained release carriers such as cellulose derivatives.

Applicants also argue against this rejection on the ground that the Bremer et al patent recites that glucosidase and/or amylase inhibitors, used in monotherapy in combination with a reduction diet bring about "practically no weight lose and further states it is the combined use of glucosidase and/or amylase inhibitors in combination with a lipase inhibitor that results in weight loss. Applicants argue that this statement in the Bremer et al patent teaches against Applicants claimed method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient. This argument is not persuasive since Applicants have not claimed the administration of acarbose, alone, to stimulate weight loss. This statement only indicate that the administration of acarbose alone do not stimulate weight loss and establishes that a composition comprising acarbose is required to stimulate weight loss. The acarbose formulation used by applicants comprises other ingredients, which is

anticipated by the Bremer et al patent. Arguments presented by Applicants with regard to the use a lipase inhibitor in the composition is not persuasive since the language set forth in the claims as currently written do not exclude the presence of other active ingredients with the composition.

Applicants further argue that the Patel et al patent gives no indication that acarbose cellulose ether-based coating may be used for the treatment of obesity. This argument is not persuasive since the rejection is base on the combination of Patel et al with the Bremer et al patent, which does indicate a treatment for obesity. Accordingly, the rejection of Claims 28-42 under 35 U.S.C. 103(a) as being unpatentable over the Bremer et al patent in view of the Patel et al patent is maintained for the reasons of record.

Reference Showing The State Of The Art

17. If Applicants intended for Claim 28 to comprise acarbose as the only active ingredient to be administered to a patient to stimulate weight loss, a review of the Rosner patent (US No. 6,387,361) is suggested, which discloses a method of controlling weight in a human comprising administering to humans with a meal of carbohydrate containing food an amount of acarbose sufficient to lower carbohydrate absorption. This patent is only cited to show the state of the art, but qualifies as art against the instantly claimed invention.

Summary

18. All the pending claims are rejected.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

20. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reach on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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JAMES O. WILSON
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